

WHAT IS CLAIMED IS:

- 1) A bilayer solid composition comprising (1) a first layer comprising an anti-allergic effective amount of desloratadine and a desloratadine-protective amount of a pharmaceutically acceptable water insoluble basic calcium, magnesium or aluminum salt, or of a desloratadine-protective amount of at least one pharmaceutically acceptable antioxidant; and (2) a second layer comprising an effective amount of pseudoephedrine or a pharmaceutically acceptable salt thereof, and a pharmaceutically acceptable excipient, and optionally, a desloratadine-protective amount of at least one pharmaceutically acceptable antioxidant.
- 2) The bilayer solid composition of claim 1 wherein the first layer is in intimate contact with the second layer
- 3) The bilayer solid composition of claim 1 wherein at least about 80% of the desloratadine dissolves in a 0.1N HCl solution at 37°C in about 45 minutes.
- 4) The bilayer solid composition of claim 1 wherein total amount of desloratadine degradation products is less than or equal to about 2.0 % by weight.
- 5) The bilayer solid composition of claim 1 wherein about 0.1 % to about 10% of at least one pharmaceutically acceptable antioxidant is present in the first layer.
- 6) The bilayer solid composition of claim 1 wherein a desloratadine-protective amount of at least one pharmaceutically acceptable antioxidant is present in the second layer.
- 7) The bilayer solid composition of claim 1 wherein a pharmaceutically acceptable water insoluble basic calcium, magnesium or aluminum salt antioxidant is present in the first layer.

8) The bilayer solid composition of claim1 wherein the anti-allergic effective amount of desloratadine in the first layer is about 2.5 mg.

9) The bilayer solid composition of claim1 wherein the anti-allergic effective amount of desloratadine in the first layer is about 5.0 mg.

10) The bilayer solid composition of claim 1 wherein two pharmaceutically acceptable antioxidants are present in the first layer.

10 11) A bilayer solid composition comprising (1) a first layer comprising an anti-allergic effective amount of desloratadine and desloratadine-protective amount of a pharmaceutically acceptable water insoluble basic calcium, magnesium or aluminum salt, and (2) a second layer comprising an effective amount of pseudoephedrine or a pharmaceutically acceptable salt thereof.

15 12) The bilayer solid composition of claim 11 wherein the first layer is in intimate contact with the second layer

13) The bilayer solid composition of claim11 wherein at least about 80% of the desloratadine dissolves in a 0.1N HCl solution at 37°C in about 45 minutes.

20 14) The bilayer solid composition of claim 11 wherein total amount of desloratadine degradation products is less than or equal to about 2.0 % by weight.

25 15) The bilayer solid composition of claim 11 wherein the anti-allergic effective amount of desloratadine in the first layer is about 2.5 mg.

16) The bilayer solid composition of claim 11 wherein the anti-allergic effective amount of desloratadine in the first layer is about 5.0 mg.

17) A bilayer solid composition comprising (1) a first layer comprising an anti-allergic effective amount of desloratadine and a desloratadine-protective amount of at least one pharmaceutically acceptable antioxidant; and (2) a second layer comprising an effective amount of pseudoephedrine or a pharmaceutically acceptable salt thereof, a pharmaceutically acceptable excipient, and a desloratadine-protective amount of at least one pharmaceutically acceptable antioxidant, and wherein total amount of desloratadine degradation products is less than or equal to about 2.0 % by weight..

5 18) The bilayer solid composition of claim 17 wherein the first layer is in intimate contact with the second layer

10 19) The bilayer solid composition of claim 17 wherein at least about 80% of the desloratadine dissolves in a 0.1N HCl solution at 37°C in about 45 minutes.

15 20) The bilayer solid composition of claim 17 wherein about 0.1 % to about 10% of at least one pharmaceutically acceptable antioxidant is present in the first layer.

20 21) The bilayer solid composition of claim 17 wherein the anti-allergic effective amount of desloratadine in the first layer is about 2.5 mg.

22) The bilayer solid composition of claim 17 wherein the anti-allergic effective amount of desloratadine in the first layer is about 5.0 mg.

25 23) The bilayer solid composition of claim 17 wherein two pharmaceutically acceptable antioxidants are present in the first layer.

30 24) A bilayer solid composition comprising (a) an immediate release first layer comprising an anti-allergic effective amount of desloratadine and at least one pharmaceutically acceptable excipient and (b) a sustained release second layer comprising an effective amount of a pseudoephedrine, or a pharmaceutically acceptable salt thereof, and a pharmaceutically acceptable excipient, and wherein

total amount of desloratadine degradation products is less than or equal to about 2% by weight, and wherein at least about 80% of the desloratadine dissolves in a 0.1N HCl solution at 37°C in about 45 minutes.

5 25) The bilayer solid composition of claim 24 wherein total amount of desloratadine degradation products is less than or equal to about 1.5 % by weight.

26) A bilayer solid composition comprising a first layer and a second layer, wherein the first layer is an immediate release layer comprising:

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<u>INGREDIENT</u>	<u>mg/composition</u>
Desloratadine, micronized	2.5
Corn Starch	11.0
Dibasic Calcium Phosphate Dihydrate	53.0
15 Microcrystalline Cellulose	30.22
Talc	3.0
Dye FD+C Blue No. 2 Aluminium Lake	<u>0.28</u>
	TOTAL 100.00

and

20 and wherein the second layer is an sustained release layer comprising

<u>INGREDIENT</u>	<u>mg/composition</u>
Pseudoephedrine Sulfate	120.0
Hydroxypropyl Methylcellulose	105.0
25 Microcrystalline cellulose	100.0
Povidone	18.0
Silicon Dioxide	5.0
Magnesium stearate	<u>2.0</u>
	TOTAL 350.0

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and wherein total amount of desloratadine degradation products is less than or equal to about 2% by weight .

27) The bilayer solid composition of claim 26 wherein at least about 80% of the desloratadine dissolves in a 0.1N HCl solution at 37°C in about 45 minutes.

5 28) A bilayer solid composition comprising (1) a first layer comprising 2.5 mg of desloratadine and desloratadine-protective amount of a pharmaceutically acceptable water insoluble basic calcium, magnesium or aluminum salt, and (2) a second layer comprising 120 mg of pseudoephedrine or a pharmaceutically acceptable salt thereof, and a pharmaceutically acceptable excipient, and wherein
10 total amount of desloratadine degradation products is less than or equal to about 2% by weight

29) The bilayer solid composition of claim 28 wherein at least about 80% of the desloratadine dissolves in a 0.1N HCl solution at 37°C in about 45 minutes.

15 30) A bilayer solid composition comprising (1) a first layer comprising 5 mg of desloratadine and desloratadine-protective amount of at least one pharmaceutically acceptable antioxidant, and (2) a second layer comprising 120 mg of pseudoephedrine or a pharmaceutically acceptable salt thereof, and a
20 pharmaceutically acceptable excipient, and wherein total amount of desloratadine degradation products is less than or equal to about 2% by weight.

31) The bilayer solid composition of claim 30 wherein at least about 80% of the desloratadine dissolves in a 0.1N HCl solution at 37°C in about 45 minutes

25 32) A bilayer solid composition comprising a first layer and a second layer, wherein the first layer is an immediate release layer comprising:

	<u>INGREDIENT</u>	<u>mg/composition</u>
30	Desloratadine, micronized	5.0
	Corn Starch NF/Ph.Eur.	11.0

Dibasic Calcium Phosphate Dihydrate USP/Ph.Eur.	53.0
Microcrystalline Cellulose NF/Ph.Eur./JP	27.72
Talc USP/Ph.Eur.	3.0
Dye FD&C Blue No. 2 Aluminium Lake 5627	0.28
5	TOTAL 100.00

and wherein the second layer is a sustained release layer comprising:

	<u>INGREDIENT</u>	<u>mg/composition</u>
10	Pseudoephedrine Sulfate USP	120.0
	Hydroxypropyl Methylcellulose 2208,1000,00cps	
	USP/Ph.Eur.	105.0
	Microcrystalline Cellulose NF/Ph.Eur./JP	100.0
15	Povidone USP/Ph.Eur./JP	18.0
	Silicon Dioxide NF	5.0
	Magnesium Stearate NF/Ph.Eur.JP(Non-Bovine)	<u>2.0</u>
	TOTAL	350.0
	TOTAL TABLET	450.0
20	and wherein total amount of desloratadine degradation products in the composition is less than or equal to about 2% by weight.	

33) The bilayer solid composition of claim 32 wherein at least about 80% of the desloratadine dissolves in a 0.1N HCl solution at 37°C in about 45 minutes.

25 34) A bilayer solid composition comprising a first layer and a second layer, wherein the first layer is an immediate release layer comprising:

	<u>INGREDIENT</u>	<u>mg/composition</u>
30	Desloratadine, micronized	5.0
	Corn Starch NF/Ph.Eur.	36.0
	Microcrystalline Cellulose NF/Ph.Eur./JP	132.7

Edetate Disodium USP	10.0
Citric Acid Anhydrous,USP	10.0
Stearic Acid, NF.	6.0
Dye FD&C Blue No. 2 Aluminium Lake 5627	0.30
5 Water Purified USP/Ph.Eur.	---
	TOTAL
	200.00 :

and wherein the second layer is a sustained release layer comprising

	<u>INGREDIENT</u>	<u>mg/composition</u>
10	Pseudoephedrine Sulfate USP	120.0
	Hydroxypropyl Methylcellulose 2208,1000,00cps	
	USP/Ph.Eur(K100M).	105.0
	Microcrystalline Cellulose NF/Ph.Eur./JP	99.5
15	Povidone, USP	18.0
	Silicon Dioxide NF	5.0
	Magnesium Stearate NF/Ph.Eur.JP(Non-Bovine)	2.5
	Water Purified USP/Ph.Eur.	---
	Alcohol USP/3A Alcohol	---
20		TOTAL
		350.0

TOTAL Tablet Weight 550.0;

and wherein total amount of desloratadine degradation products in the composition is less than or equal to about 2% by weight.

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35) The bilayer solid composition of claim 33 wherein at least about 80% of the desloratadine dissolves in a 0.1N HCl solution at 37°C in about 45 minutes.

36) A bilayer solid composition comprising a first and second layer, wherein the

30 first layer is an immediate release first layer comprises:

	<u>INGREDIENT</u>	<u>mg/composition</u>
	Desloratadine, micronized	2.5
5	Corn Starch NF/Ph.Eur.	18.0
	Microcrystalline Cellulose NF/Ph.Eur./JP	66.35
	Eddate Disodium	5.0
	Citric Acid	5.0
	Stearic Acid USP/Ph.Eur.	3.0
10	Dye FD&C Blue No. 2 Aluminium Lake 5627	<u>0.15</u>
	TOTAL	100.00

and wherein the second layer is a sustained release layer comprising:

	<u>INGREDIENT</u>	<u>mg/composition</u>
15	Pseudoephedrine Sulfate USP	120.0
	Hydroxypropyl Methylcellulose (K100M)	
	2208, 1000,00cps USP/Ph.Eur.	105.0
	Microcrystalline Cellulose NF/Ph.Eur./JP	99.5
20	Povidone USP K-30	18.0
	Silicon Dioxide NF	5.0
	Magnesium Stearate NF/Ph.Eur.JP(Non-Bovine)	<u>2.5</u>
	TOTAL	350
	TOTAL Tablet Weight	450.0

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and wherein total amount of desloratadine degradation products is less than or equal to about 2% by weight.

37) The bilayer solid composition of claim 36 wherein at least about 80% of the
 30 desloratadine dissolves in a 0.1N HCl solution at 37°C in about 45 minutes.

38) A method of treating allergic and inflammatory conditions of the upper and lower airway passages and skin which comprises administering to a patient in need of such treating an effective amount of the bilayer solid composition of claim 1.

5 39) A method of treating nasal congestion associated with allergic and inflammatory conditions of the upper and lower airway passages and skin which comprises administering to a patient in need of such treating an effective amount of the bilayer solid composition of claim 1.

10 40) A method of treating urticaria which comprises administering to a patient in need of such treating an effective amount of the bilayer solid composition of claim 1.

15 41) A method of treating the nasal and non-nasal symptoms of perennial and seasonal allergic rhinitis which comprises administering to a patient in need of such treating an effective amount of the bilayer solid composition of claim 1.